

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|--------|----|---|--------------------------|------------------------|
| <p>Substitute for form 1449/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(Use as many sheets as necessary)</i></p> | | | | Complete If Known | |
| | | | | Application Number | 10/552,314-Conf. #1865 |
| | | | | Filing Date | September 5, 2006 |
| | | | | First Named Inventor | Annie BARDAT |
| | | | | Art Unit | 1644 |
| Examiner Name | Y. Kim | | | | |
| Sheet | 1 | of | 2 | Attorney Docket Number | 0040-0158PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------------|-----------------------|--|--------------------------------|--|--|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| AA* | US-5,945,098 | 08-31-1999 | Sarno et al. | | |
| | | | | | |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|-----------------------------------|--|--|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | |
| BA | WO-97/04801-A1 | 02-13-1997 | GENENTECH INC | | |
| BB | WO-02/092632 | 11-21-2002 | LAB FRANCAIS DU FRACTIONNEMENT | | |
| BC | WO-2002/013860 | 02-21-2002 | CHUGAI PHARMACEUTICAL CO LTD | | ✓ |
| BD | JP-61-191622 | 08-26-1986 | Green Cross Corp | | ✓ |
| BE | EP-0196761-A2 | 10-08-1986 | GREEN CROSS CORP | | |
| BF | JP-5-025058 | 02-02-1993 | HAGIWARA YOSHIHIDE | | ✓ |
| BG | EP-0597101 | 05-18-1994 | HAGIWARA HIDEAKI | | |
| BH | JP-63-088197 | 04-19-1988 | Tosoh Corp | | ABS |
| BI | JP-9-500894 | 01-28-1997 | | | ABS |
| BJ | WO-98/44948-A2 | 10-15-1998 | CANGENE CORP | | |
| BK | JP-11-510170 | 09-07-1999 | | | ✓ |
| BL | EP-1314437 | 05-28-2003 | CHUGAI PHARMACEUTICAL CO LTD | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| | | | | | |
|------------------------------|---|----|---|--------------------------|------------------------|
| Substitute for form 1449/PTO | | | | Complete If Known | |
| | | | | Application Number | 10/552,314-Conf. #1865 |
| | | | | Filing Date | September 5, 2006 |
| | | | | First Named Inventor | Annie BARDAT |
| | | | | Art Unit | 1644 |
| | | | | Examiner Name | Y. Kim |
| Sheet | 2 | of | 2 | Attorney Docket Number | 0040-0158PUS1 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|-----------------------|--|--|--|--------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | ² |
| | CA | BLEEKER, Wim K. et al., "Vasoactive side effects of intravenous immunoglobulin preparations in a rat model and their treatment with recombinant platelet-activating factor acetylhydrolase," <i>Blood</i> , March 1, 2000, Vol. 95, No. 5, pp. 1856-1861. | | | |
| | CB | PIKAL, Michael J., "Freeze-drying of proteins, part II: Formulation selection," <i>BioPharm</i> , October 1990, Vol. 3, No. 9, pp. 26-30. | | | |
| | CC | ARAKAWA, Tsutomu et al., "Protein-solvent interactions in pharmaceutical formulations," <i>Pharmaceutical Research</i> , 1991, Vol. 8, No. 3, pp. 285-291. | | | |
| | CD | OSTERBERG, Thomas et al., "Development of a freeze-dried albumin-free formulation of recombinant factor VIII SQ," <i>Pharmaceutical Research</i> , 1997, Vol. 14, No. 7, pp. 892-898. | | | |
| | CE | GUO, Wei et al., "Raman evidence that the lyoprotectant poly(ethylene glycol) does not restore nativity to the heme active site of horseradish peroxidase suspended in organic solvents," <i>Biomacromolecules</i> , 2002, Vol. 3, No. 4, pp. 846-849. | | | |
| | CF | CHIDWICK, K. et al., "Clinical experience with a new solvent detergent-treated intravenous immunoglobulin free of hypotensive effects," <i>Vox Sanguinis</i> , 1999, Vol. 77, No. 4, pp. 204-209. | | | |
| | CG | COHN, E. J. et al., "Preparation and properties of serum and plasma proteins. IV. A system for the separation into fractions of the protein and lipoprotein components of biological tissues and fluids," <i>J. Am. Chem. Soc.</i> , March 1946, Vol. 68, pp. 459-475. | | | |
| | CH | KISTLER, P. et al., "Large scale production of human plasma fractions. Eight years experience with the alcohol fractionation procedure of Nitschmann, Kistler and Lergier," <i>Vox Sang.</i> , 1962, Vol. 7, pp. 414-424. | | | |
| | CI | STEINBUCH, M. et al., "Isolement de l'immunoglobuline IgG du plasma humain a l'aide de l'acide caprylique," <i>Rev. Fr. Etud. Clin. Biol.</i> , Dec. 1969, Vol. 14, No. 10, pp. 1054-1058. | | | |
| | CJ | FERNADES, Peter M. et al., "Preparation of a stable Intravenous gamma-globulin: Process design and scale-up," <i>Vox Sang.</i> , 1980, Vol. 39, No. 2, pp. 101-112. | | | |
| | CK | LEVINE, Howard L. et al., "The use of surface tension measurements in the design of antibody-based product formulations," <i>Journal of Parenteral Science & Technology</i> , 1991, Vol. 45, No. 3, pp. 160-165. | | | |
| | CL | Pharmacopee Europeenne, 4eme edition, chap. <<Immunoglobuline humaine normale pour administration par voie intraveineuse>>, Methode 2.6.17. | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.